



Canadian
Manufacturers &
Exporters

Manufacturiers et
Exportateurs du
Canada

July 13, 2004

Docket No: 2002N-0278

Mr. William Hubbard
Senior Associate Commissioner for Policy and Planning
Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Dear Mr. Hubbard:

Canadian Manufacturers & Exporters (CME) welcomes the opportunity to provide comments on the *Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002*, as published on April 14, 2004 by the Food and Drug Administration and the Department of Health and Human Services, Docket No 2002N-0278.

CME represents Canada's businesses engaged in manufacturing and the export of goods and services. Our membership produces approximately seventy-five percent of Canada's manufacturing output and ninety percent of Canadian exports. The United States is the largest recipient of food exports from Canada, and production and supply chains on either side of the border are highly integrated. The United States and Canada enjoy the most successful trading relationship in the world, on which millions of jobs on both sides of the border depend.

Canadian Manufacturers & Exporters recognizes the security objectives inherent in the Bioterrorism Act, and supports the FDA's efforts to improve its ability to prevent and respond to bioterrorist threats and potential food security vulnerabilities. CME also supports the need for pre-arrival notification and seeks an implementation approach that takes into account the unique trading relationship between Canada and the U.S.

Following consultation with our members, we reemphasize the general concern that these rules do not correspond with Customs and Border Protection (CBP) rules for prior notice and that there is no contingency plan in place for noncompliant shipments. In addition, we offer the following comments:

1. CME recommends that food products subject to FDA's prior notice requirements be eligible for the full-expedited processing and information transmission benefits allowed with C-TPAT/FAST in order to avoid duplication and inconsistent application of prior notice requirements for shipments that meet the FAST stringent criteria.

This can be accomplished by enhancing coordination between CBP and FDA, allowing trained CBP/FDA officers to process food shipments through the FAST lane, and allowing FAST importers using a FAST driver and carrier importing food and/or feed products to submit prior notice to both the CBP and FDA through the existing CBP/FDA interface.

2. CME recommends that all prior notice timeframes, including the shorter timeframe applicable to FAST members, be harmonized between the CBP and FDA.

3. CME recommends that the CBP and FDA coordinate security and verification processes in C-TPAT to address the additional security concerns of the FDA in order to allow C-TPAT/FAST members expedited processing of food and feed shipments in addition to CBP shipments.
4. CME recommends that FDA provide feedback to industry detailing areas of noncompliance and compliance status.

CME hopes that these comments help the FDA develop its final rule on prior notice of imported food and encourages the continued collaboration of the FDA with the trade community in the joint fight against bioterrorism. The economies of Canada and the US are the most integrated in the world and rely heavily on free and secure trade across our border. It is critical that we work closely together to address bioterrorism concerns while also ensuring the facilitation of low-risk goods based upon the twin goals of economic and public security.

I thank you for your action on this matter and would be pleased to discuss these issues at your convenience.

Sincerely,

ORIGINAL SIGNED BY:

Perrin Beatty, President & CEO, CME

Cc: Mr. Jerry Jasinowski, President, National Association of Manufacturers;
Mr. Bob Séguin, Acting Deputy Minister, Ministry of Enterprise, Opportunity and Innovation, Ontario Ministry of Economic Development and Trade;
Members of CME